IN THE CLAIMS

This listing of claims replaces all prior versions, and listings, in this application.

Claims 1-59 (canceled)

60. (withdrawn) A process for the preparation of an N-acyl-(epi)K5-amine-O-oversulfate-derivative or of its chemically or pharmaceutically acceptable salts, which comprises

(a) treating an (epi)K5-N-sulfate-derivative, in acidic form, with a tertiary or quaternary organic base, letting the reaction mixture to stand for a time period of 30-60 minutes, maintaining the pH of the solution at a value of approximately 7 and isolating its salt with said organic base;

(b) treating said organic base salt of said (epi)K5-N-sulfate-derivative with an O-sulfation reagent in the conditions of O-oversulfation; and

(c) treating the (epi)K5-amine-O-oversulfate-derivative thus obtained with a functional derivative of a C_2-C_4 carboxylic acid and isolating the N-acyl-(epi)K5-amine-O-oversulfate-derivative.

61. (withdrawn/currently amended) The process ~~Process~~ according to claim 60, wherein said N-acyl-(epi)K5-amine-O-oversulfate is isolated in sodium salt form and optionally transformed into another chemically or pharmaceutically acceptable salt.

62. (withdrawn/currently amended) The process ~~Process~~ according claim 60, wherein, in step (a), tetrabutylammonium hydroxide is used as an organic base.

63. (withdrawn/currently amended) The process ~~Process~~ according to claim 60, wherein in step (b) the O-oversulfation is carried out in dimethylformamide utilizing 2-4 moles of O-sulfation reagent per available OH per disaccharide at a temperature of 40-60°C for 15-20 hours.

64. (withdrawn/currently amended) The process ~~Process~~ according to claim 60, wherein as starting material an (epi)K5-N-sulfate-derivative is used having a mean molecular weight from approximately 1,000 to approximately 25,000.

65. (withdrawn/currently amended) The process ~~Process~~ according to claim 60, wherein said starting material is 40-60% C5-epimerized.

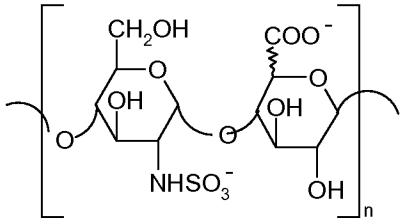
66. (withdrawn/currently amended) The process ~~Process~~ according claim 60, wherein said starting material has a mean molecular weight from approximately 1,500 to approximately 25,000.

67. (withdrawn/currently amended) The process ~~Process~~ according to claim 66, wherein said starting material has a mean molecular weight between 10,000 and 25,000.

68. (withdrawn/currently amended) The process ~~Process~~ according to claim 66, wherein said starting material has a mean molecular weight from approximately 1,500 to approximately 12,000.

69. (withdrawn/currently amended) The process ~~Process~~ according to claim 68, wherein said starting material has a mean molecular weight from approximately 1,500 to approximately 8,000.

70. (withdrawn/currently amended) The process ~~Process~~ according to claim 60, wherein as starting material an (epi)K5-N-sulfate-derivative is used consisting of a chain mixture in which at least 90% of said chains have the formula I



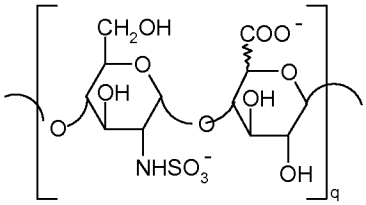
(I)

in which the glucuronic units/iduronic units ratio is from 100/0 to 40/60, n is an integer from 2 to 100 and the corresponding cation is chemically or pharmaceutically acceptable.

71. (withdrawn/currently amended) The process ~~Process~~ according to claim 70, wherein said starting material consists of a chain mixture in which at least 90% of said chains have the formula I, in which the uronic units are 40-60% consisting of iduronic acid.

72. (withdrawn/currently amended) The process ~~Process~~ according to claim 70, wherein said starting material is a LMW-(epi)K5-N-sulfate consisting of a chain mixture in which at least 90% of said chains have the formula I in which the uronic units are all consisting of glucuronic acid or are 40-60% consisting of iduronic acid, n is an integer from 3 to 15 and the corresponding cation is chemically acceptable.

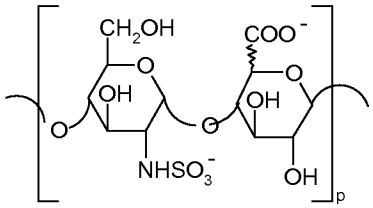
73. (withdrawn/currently amended) The process ~~Process~~ according to claim 70, wherein said starting material is a MW-(epi)K5-N-sulfate consisting of a chain mixture in which at least 90% of said chains have the formula I'



(I')

in which the uronic units are 100% consisting of glucuronic acid or 60-40% of glucuronic acid and 40-60% of iduronic acid, q is an integer from 2 to 20 and the corresponding cation is chemically or pharmaceutically acceptable.

74. (withdrawn/currently amended) The process ~~Process~~ according to claim 70, wherein said starting material is a LMW-(epi)K5-N-sulfate consisting of a chain mixture in which the preponderant species has the formula I'a

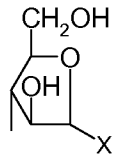


(I'a)

in which the uronic units are 100% consisting of glucuronic acid or 60-40% glucuronic and 40% to 60% of iduronic acid, p is an integer from 4 to 8.

75. (withdrawn/currently amended) The process ~~Process~~ according to claim 64, wherein said starting material is a LMW-(epi)K5-N-sulfate obtained by nitrous depolymerization of the corresponding (epi)K5-N-sulfate and subsequent reduction.

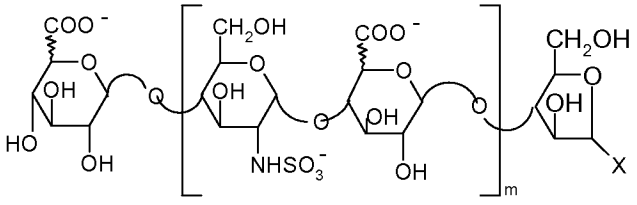
76. (withdrawn/currently amended) The process ~~Process~~ according to claim 75, wherein said starting LMW-(epi)K5-N-sulfate contains, at the reducing end of the majority of the chains in said chain mixture, a 2,5-anhydromanno unit of structure (a)



(a)

in which X represents a hydroxymethyl group.

77. (withdrawn/currently amended) The process ~~Process~~ according to claim 75, wherein as starting material a LMW-(epi)K5-N-sulfate is used consisting of chain mixtures in which the preponderant species is a compound of formula I'b



(I'b)

in which X is hydroxymethyl, m is 4, 5 or 6, the corresponding cation is a chemically or pharmaceutically acceptable ion, the uronic units are all of glucuronic acid or the

glucuronic and iduronic units are present alternately, starting with a glucuronic or iduronic unit.

78. (withdrawn/currently amended) The process ~~Process~~ according to claim 60, wherein said starting (epi)K5-N-sulfate-derivative is utilized in sodium salt form.

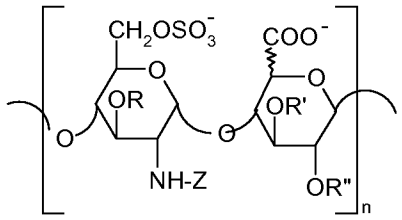
79. (previously presented) A 100% acylated N-acyl-epiK5-amine-O-oversulfate-derivative, in which acyl is a (C_2-C_4)acyl, having an iduronic acid content of 20-60%, a mean molecular weight from approximately 2,000 to approximately 45,000 and a sulfation degree of at least 3.4, or one of its chemically or pharmaceutically acceptable salts.

80. (currently amended) The [[An]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 79, whose mean molecular weight is between approximately 15,000 and approximately 45,000.

81. (currently amended) The [[An]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 79, whose mean molecular weight is between approximately 4,500 and approximately 8,500.

82. (currently amended) The [[An]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 79, wherein said degree of sulfation is from 3.4 to 3.8.

83. (previously presented) A 100% N-acylated N-acyl-epiK5-amine-O-oversulfate-derivative consisting of chain mixtures in which at least 90% of said chains have the formula IV

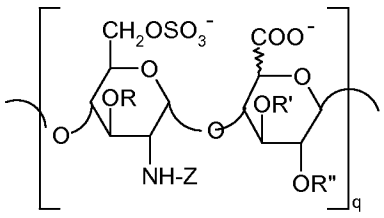


(IV)

in which the uronic units are 20-60% consisting of iduronic acid, n is an integer from 2 to 100, R, R' and R" are hydrogen or SO_3^-, Z is$(C_2\text{-}C_4)$acyl, the degree of sulfation is at least 3.4 and the corresponding cation is chemically or pharmaceutically acceptable.

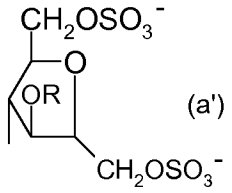
84. (currently amended) The [[A]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 83, consisting of a chain mixture in which at least 90% of said chains have the formula IV in which the uronic units are 40-60% consisting of iduronic acid, n is a integer from 3 to 100, with a mean molecular weight from approximately 2,000 to approximately 45,000, R is at least 40% SO_3^-, R' and R" are both SO_3^- or one is hydrogen and the other is 5-10% SO_3^- in monosulfate glucuronic acid and 10-15% SO_3^- in monosulfate iduronic acid and the corresponding cation is chemically or pharmaceutically acceptable.

85. (currently amended) The [[A]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 83, which is a LMW-N-acyl-epiK5-O-oversulfate consisting of a chain mixture in which at least 90% of said chains have the formula IV'



(IV')

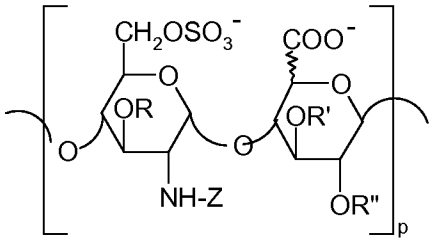
in which q is an integer from 2 to 20, R, R' and R" represent hydrogen or an SO_3^- group for a degree of sulfation from 3.55 to 4, Z is $(C_2\text{-}C_4)$acyl, bearing a sulphated 2,5-anhydromannitol unit of structure (a')



(a')

wherein R represent hydrogen or SO_3^-, in the majority of the chains in said chain mixture, and the corresponding cation is chemically or pharmaceutically acceptable.

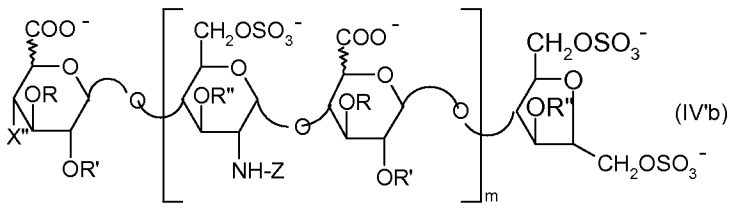
86. (currently amended) The [[A]] LMW-N-acyl-epiK5-amine-O-oversulfate according to claim 85, consisting of a chain mixture in which the preponderant species is a compound of formula IV'a



(IV'a)

in which p is an integer from 4 to 8, R, R' and R" are hydrogen or an SO_3^- group for a degree of sulfation from 3.55 to 4, Z is (C_2-C_4)acyl, and the corresponding cation is chemically or pharmaceutically acceptable.

87. (currently amended) The [[A]] LMW-N-acyl-epiK5-amine-O-oversulfate according to claim 86, wherein said preponderant species is a compound of formula IV'b



(IV'b)

in which R, R' and R" are hydrogen or SO_3^-, Z is (C_2-C_4)acyl, X" is OH or OSO_3^-, m is 4, 5 or 6, for a degree of sulfation from 3.55 to 4, the uronic units are present alternately, starting with a glucuronic or iduronic unit, and the corresponding cation is chemically or pharmaceutically acceptable.

88. (currently amended) The [[A]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 79 in which the substituent (C_2-C_4)acyl is selected from the group consisting of acetyl, (2-carboxy)acetyl, (2-methoxycarbonyl)acetyl, (2-ethoxycarbonyl)acetyl, propionyl, (3-carboxy)propionyl, N-(3-methoxycarbonyl)propionyl and (3-ethoxycarbonyl)propionyl.

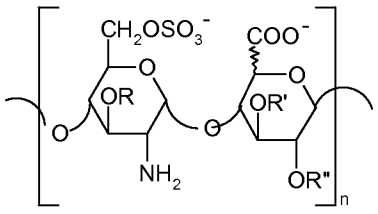
89. (currently amended) The [[An]] N-acyl-epiK5-amine-O-oversulfate-derivative according to claim 79, wherein said salt is an alkaline metal or alkaline-earth metal, ammonium, (C_1-C_4)tetraalkylammonium, aluminum or zinc salt.

Claims 90-100 (canceled)

101. (previously presented) A pharmaceutical composition including, as an active ingredient, an (epi)K5-amine-O-oversulfate-derivative or one of its pharmaceutically acceptable salts, isolated in sodium salt form and optionally transformed into another pharmaceutically acceptable salt, in mixture with a pharmaceutical excipient.

102. (currently amended) The composition ~~Composition~~ according to claim 101, wherein said active ingredient is an (epi)K5-amine-O-oversulfate-derivative having a mean molecular weight from approximately 4,500 to approximately 40,000.

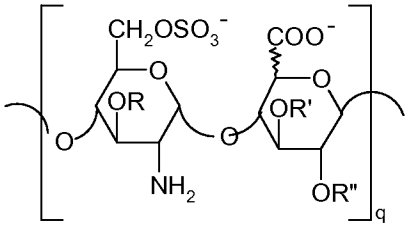
103. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 101, in which said active ingredient is an (epi)K5-amine-O-oversulfate-derivative consisting of a chain mixture in which at least 90% of said chains have the formula II



(II)

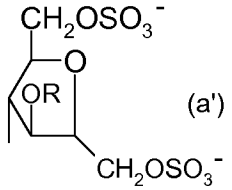
in which n is an integer from 2 to 100, R, R' and R" are hydrogen or SO_3^-, the uronic units are all of glucuronic acid, for a degree of sulfation from 2.2 to 3, or are 20-60% consisting of iduronic acid, for a sulfation degree of at least 3.4, and the corresponding cation is pharmaceutically acceptable.

104. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 103, wherein said active ingredient is a LMW-epiK5-amine-O-oversulfate consisting of a chain mixture in which at least 90% of said chains have the formula II'



(II')

in which q is an integer from 2 to 20, R, R' and R" are hydrogen or SO_3^-, the uronic units are 20-60% those of iduronic acid, for a degree of sulfation from 3.55 to 4, and bearing a sulphated 2,5-anhydromannitol unit of structure (a')

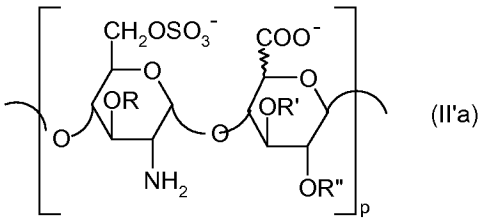


(a')

wherein R represent hydrogen or SO_3^-, in the majority of the chains in said chain mixture.

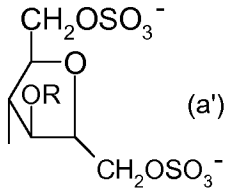
105. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 104, wherein, in said chain mixture of formula II', the uronic units are 40-60% consisting of iduronic acid, R is at least 40% SO_3^-, R' and R" are both SO_3^- or one is hydrogen and the other is 5-10% SO_3^- in glucuronic acid and 10-15% SO_3^- in iduronic acid, n is an integer from 3 to 15, with a mean molecular weight from approximately 4,000 to approximately 8,000.

106. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 104, wherein said LMW-epiK5-amine-O-oversulfate is consisting of a chain mixture in which the preponderant species has the formula II'a



(II'a)

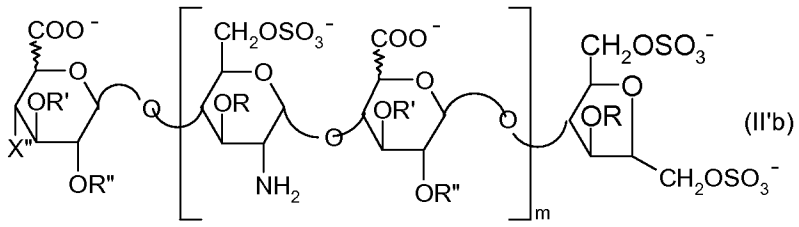
in which p is an integer from 4 to 8, R, R' and R" are as defined above, the degree of sulfation is from 3.55 to 4, said preponderant species bearing a sulphated 2,5-anhydromannitol unit of structure (a')



(a')

wherein R represent hydrogen or SO_3^-, in the majority of its chains in said chain mixture and the corresponding cation is pharmaceutically acceptable.

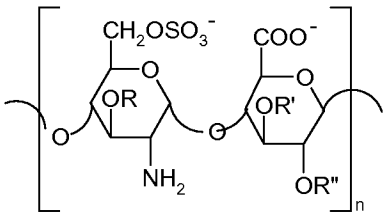
107. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 106, wherein said preponderant species is a compound of formula II'b



(II'b)

in which R, R' and R" are hydrogen or SO_3^-, X" is OH or OSO_3^-, m is 4, 5 or 6, the uronic units are 40-60% consisting of iduronic acid, for a degree of sulfation from 3.55 to 4, the iduronic units being present alternately, starting with a glucuronic or iduronic unit, and the corresponding cation is a pharmaceutically acceptable ion.

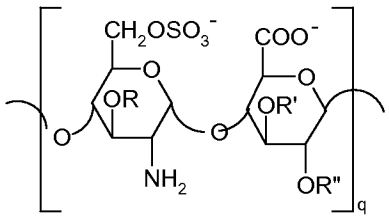
108. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 101 including, as an active ingredient, a K5-amine-O-oversulfate-derivative consisting of a chain mixture in which at least 90% of said chains have the formula III



(III)

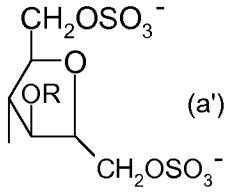
in which n is a integer from 2 to 100, R, R' and R" are hydrogen or SO_3^-, the degree of sulfation is at least 2.2, and the corresponding cation is pharmaceutically acceptable.

109. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 108, wherein said active ingredient is a LMW- K5-amine-O-oversulfate consisting of a chain mixture in which at least 90% of said chains have the formula III'



(III')

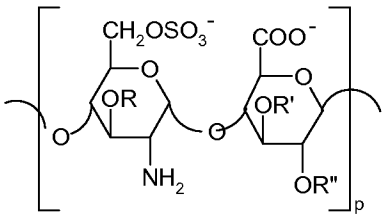
in which q is an integer from 2 to 20, R, R' and R" represent hydrogen or a SO_3^- group for a sulfation degree of at least 2.2, and at the reducing end of the majority of the chains in said chain mixture presents a sulphated 2,5-anhydromannitol unit of structure (a')



(a')

wherein R represents hydrogen or SO_3^-.

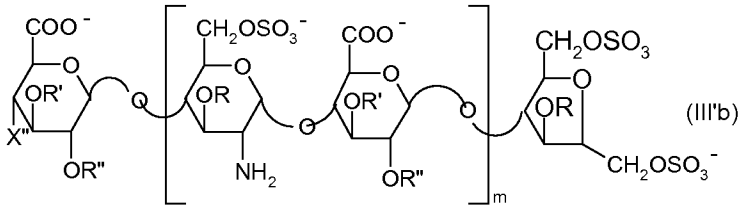
110. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 109, wherein said LMW-K5-amine-O-oversulfate consists of a chain mixture in which the preponderant species has the formula III'a



(III'a)

in which p is an integer from 4 to 8, R, R' and R" are as defined above, the degree of sulfation being from 2.2 to 3.

111. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 106, wherein said preponderant species is a compound of formula III'b



(III'b)

in which R, R' and R" are hydrogen or SO_3^-, X" is OH or OSO_3^-, for a degree of sulfation from 2.2 to 3, m is 4, 5 or 6 and the corresponding cation is a pharmaceutically acceptable ion.

112. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 101, wherein said pharmaceutically acceptable salt or cation is sodium, potassium, calcium, magnesium or zinc.

113. (currently amended) The composition ~~Pharmaceutical composition~~ according to claim 101, which is in the form of cream, ointment, liniment, gel, foam, balsam, vaginal pessary, suppository, solution or suspension for local administration.

114. (previously presented) A pharmaceutical composition containing, as an active ingredient, a pharmacologically active amount of a LMW-(epi)K5-N-sulfate basically free of acetyl groups, or of one of its pharmaceutically acceptable salts, in mixture with a pharmaceutical excipient.

Claim 115 (canceled)